NOV 15 2013

510(k) SUMMARY

The 510(k) Summary is submitted as required by section 807.92(a)

SPONSER: Volcano Corporation
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CONTACT/ SUBMITTER: Elaine Alan
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DATE SUBMITTED: September 30, 2013

DEVICE: Volcano s5™/s5i® CORE and CORE Mobile Series Precision Guided Therapy Systems

Trade Name: Volcano s5™/s5i® CORE and CORE Mobile Series Precision Guided Therapy Systems

Common Name: Ultrasonic pulsed echo imaging system

Classification and Product Codes:

CFR Number	Class	Product Code
892.1560 Ultrasonic pulsed echo imaging system	II	IYO
870.1110 Blood Pressure Computer	II	DSK
870.2900 Patient Transducer and Electrical Cable	II	DSA

PREDICATE DEVICE: K123898, Volcano s5™s5i® Intravascular Ultrasound Imaging System

DEVICE DESCRIPTION

The Volcano s5 and CORE Series Precision Guided Therapy Systems are currently available in 2 configurations: (1) a tower or a portable model, (2) an integrated model.

The Volcano s5i® and CORE™ Precision Guided Therapy Systems are the integrated configurations that are integrated in the catheterization (cath) laboratory, meaning that the CPU is located outside the cath lab and the controls and accessories are cabled in a trench under the floor into the cath lab for use on the patient. Some models of this configuration have the cables from the trench consolidated through the Connection Box

located in the cath lab which then distributes connections to all the s5i/CORE accessories and bedside peripherals.

The Volcano s5™ and CORE™ Mobile tower systems are the tower/portable (roll-around or mobile) versions of the integrated system. These systems can be rolled into the cath lab itself and the accessories and bedside peripherals directly connect to the system. There are two (2) operating modes available on both the integrated as well as the tower models of the Volcano Precision Guided Therapy Systems, namely: (1) the Intravascular Ultrasound (IVUS) imaging mode and (2) the Fractional Flow Reserve (FFR) pressure mode.

As an accessory to the currently cleared s5 Series/CORE Systems , the Volcano LoMap is intended to allow the systems to interface with physiology monitors/hemodynamic monitoring equipment and aortic transducers for pressure level amplification.

INDICATIONS FOR USE
The Volcano s5™ Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo® is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion. VH® IVUS is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature. As an adjunct to conventional angiographic procedures to

provide an image of the vessel lumen and wall structures. The pullback feature of the PIMr withdraws the imaging core within the protective sheath for a maximum of 15 cm.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The proposed device is identical to the currently marketed device except for the addition of a new optional accessory, the Volcano LoMap. The Volcano LoMap acts as an interface between Volcano s5 Series/CORE Systems and hemodynamic systems in the catheterization laboratory. The technological characteristics, fundamental scientific technology, and indications for use remain unchanged.

PERFORMANCE DATA: Non-clinical Testing

Applicable testing was performed as require by the Quality System to evaluate the modification to the Volcano s5 Series/CORE Systems. The following tests were conducted:

- Reliability HALT
- Electrical Safety
- Electromagnetic Compatibility
- Software Tests

The test results were found to be acceptable by the respective test plans and protocols.

Biocompatibility testing was not required as the proposed accessory does not come in contact with the patient or any fluid path.

PERFORMANCE DATA: Clinical Testing

No human or animal clinical testing was performed for this premarket notification.

Conclusion

Completion of these tests concluded that the proposed Volcano s5 Series/CORE Systems are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 15, 2013

Volcano Corporation
Elaine Alan
1 Fortune Dr
Billerica, MA 01821 US

Re: K133142
Trade/Device Name: Volcano LoMap, Volcano LoMap Option Kit For Mobile System, Volcano LoMap Option for Integrated System, Volcano S5 Precision
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO
Dated: September 30, 2013
Received: October 17, 2013

Dear Elaine Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133142

Device Name: Volcano s5§/s5i® CORE and CORE Mobile Series Precision Guided Therapy Systems

Indications for Use:

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Prescription Use ____X_____ AND/OR Over-the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Digitally signed by Owen P. Faris -S
Date: 2013.11.15 11:13:58 -05'00'